PRIYAN INTERNATIONAL LAB AND TECHNOLOGY

(Reference Material Producer as per International Standard ISO : 17034)

2nd and 3rd Floor, C-247, Sector-10, Noida, Gautam Buddha Nagar, Uttar Pradesh-201301

Tel No. 0120-3684527, Mob.: 8882764797

Mail: priyanintlabtech@gmail.com, Web: www.priyaninternationallabtech.com

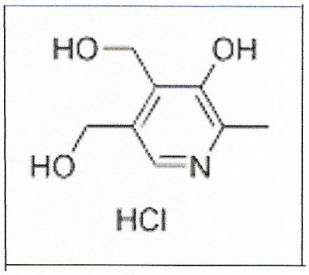
CRM CERTIFICATE

Format No: PILT/QSP/055/00/FMT/02

Certificate No: PILT/CRM/P-005/23/015

PYRIDOXINE HYDROCHLORIDE

STRUCTURE:



DESCRIPTION & IDENTIFICATION:

Batch No.: PILTRS/23/01/015	**Ref./Product No.**: P-005
Unit Quantity: 1 gm	**Chemical Formula**: $C_8H_{11}NO_3.HCl$
Molecular Weight: 205.64 g/mol	**Assigned Value(Purity)**: 99.7 % w/w or 0.997 mg per mg on as is basis
Date of Release: 21/02/2024	**u_{CRM}(%)** = 0.16 %
Validity Date: 20/02/2027	**Method:** IP 2022
Date of Issue: 20/06/2024	**Storage**: Keep container tightly closed, protected from light and store between 2°C to 8°C temp.

UNCERTAINTY:

The assigned uncertainty covers uncertainty contribution from characterization, in homogeneity, storage & transport stability etc. (wherever applicable), is the combined standard uncertainty, calculated using a coverage factor (K= 2) which gives a level of confidence of approx. 95%. As per ISO 17034:2016 & ISO Guide 35, for this pharmaceutical standard assigned uncertainty value is considered to be negligible w.r.t. defined limits of method specific assays for which the PILTRM/CRM is used.

PLATINUM PLUS ISO 17034 Accredited Reference Material Producer
ACCAB
ACCAB/IN/RMP/1084

//PILT// ISO:17034 Accredited as RM Producer and Testing Laboratory ISO/IEC:17025

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METROLOGICAL TRACEABILITY AND MEASUREMENT METHODS:

NIST or other traceable standards are used for calibration and performance verification of instruments. The assigned value is traceable to SI units through the use of Primary Standard Mass Balance Methods (Physical and chemical). Characterization was done by the combination of Primary Reference Methods viz. NMR, LCMS, FTIR with use of pure substance/traceable RM/CRM in compliance with ISO Guide 35 & ISO/IEC: 17025.

Specification and method used Indian pharmacopoeia.
CRM/RM lot IPRS/19/19 is used for the comparison.

COMMUTABILITY: Not Applicable

INTENDED USE:

PILTRM/CRM is intended for use in product/material testing/calibration including R&D, Validation or Quality Control of Analytical Methods with specified quantity. This Material cannot be used as "Drug" or household.

INSTRUCTION FOR HANDLING & USE:

Allow the sealed container to equilibrate at room temperature before opening for use. Do not dry, use "On as is Basis". Once the container has been opened, Stability of content, value cannot be guaranteed. It is for immediate use. Read MSDS before use.

VALIDITY:

Stated Validity is apply, when material stored under recommended conditions with proper handling. Any change in assigned value due to stability/retesting/review etc. or validity extension/revalidation/Updates, will be made available on our Website: www.priyaninternationallabtech.com

SAFETY INFORMATION:

Refer to the material safety data sheet.

Sandeep
20/06/2024

Approving Authority

MATERIAL SAFETY DATA SHEET (MSDS)

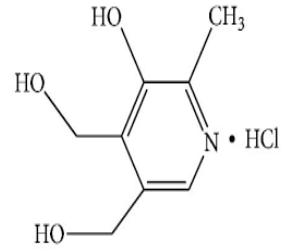
Company Information

Name of organization : **PRIYAN INTERNATIONAL LAB AND TECHNOLOGY**
Address

: **C-247, 2nd & 3rd Floor, Sector-10, Noida-201301**
Ph. No. : **0120-3684527, +91-8882764797**
Email : **priyanintlabtech@gmail.com**
Website : **www.priyaninternationallabtech.com**

Section-1. Product Identification and Composition

Product Name	: Pyridoxine HCL
Product No.	: P-005
Uses	: Laboratory chemical, Reference Material
Chemical Formula	: $C_8H_{11}NO_3HCL$
CAS No.	: 58-56-0
Molecular Weight	: 205.64 g/mol



Section-2. Hazards Identification

Potential Acute Health Effects:
Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation. Severe over-exposure can result in death.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: 3 (Not classifiable for human.) by IARC. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. The substance may be toxic to heart, gastrointestinal tract, central nervous system (CNS). Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

Section-3. First Aid Measures

Ingestion:
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Inhalation:
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician

Skin Contact:
Wash off with soap and plenty of water. Consult a physician.

Eye Contact:
Flush eyes with water as a precaution.

Section-4. Fire and Explosion Data

Flammability:
May be combustible at high temperature.
Flammable Limits:
Not available.
Auto-Ignition Temperature:
Not available.
Extinguishing media

- Suitable extinguishing media - Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- Unsuitable extinguishing media - No data available.

Protection against fire:
Wear suitable protective equipment.
Hazardous combustion products:
No data available.

Section-5. Accidental Release Measures

Environmental precautions:
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.
Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas.
Ensure adequate ventilation. Avoid breathing dust.
Methods and materials for containment and cleaning up:
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section-6. Handling and Storage

Hygiene measures:
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
Handling:
Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
Storage:
Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section-7. Exposure Controls/ Personal Protection

Respiratory Protection:
For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection:
Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solven.

Skin Protection:
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without ouching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye Protection:
Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Body protection:
Complete suit protecting against chemicals, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

General Hygiene Consideration:
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Section-8. Physical and Chemical properties

8.1 Information on basic physical and chemical properties

a) Physical state	: Powder
b) Color	: white
c) Odor	: odorless
d) Melting point/freezing point	: No data available
e) Initial boiling point and boiling range	: No data available
f) Flammability (solid, gas)	: No data available
g) Upper/lower flammability or explosive limits	: No data available
h) Flash point	: No data available
i) Auto ignition temperature	: No data available
j) Decomposition temperature	: No data available
k) pH	: No data available
l) Viscosity	: Viscosity, kinematic: No data available : Viscosity, dynamic: No data available
m) Water solubility	: No data available
n) Partition coefficient n-octanol/water	: No data available
o) Vapor pressure	: No data available
p) Density	: No data available
Relative density	: No data available
q) Relative vapor density	
r) Particle characteristics	: No data available
s) Explosive properties	: No data available
t) Oxidizing properties	: none

Section-9. Stability and Reactivity

Polymerization: Will not occur.
Stability: The product is stable.
Instability Temperature: Not available.
Conditions of Instability: Excess heat
Incompatibility with various substances: Not available.
Corrosivity: Non-corrosive in presence of glass.
Special Remarks on Reactivity: Not available.
Special Remarks on Corrosivity: Not available

Section-10. Toxicological Information

Acute toxicity
LD50 Oral - Rat - 4.000 mg/kg
Remarks: Behavioral:Convulsions or effect on seizure threshold.
Behavioral:Excitement.
(RTECS)
Inhalation: No data available
Dermal: No data available
Skin corrosion/irritation
Skin - In vitro study
Result: No skin irritation - 15 min
(OECD Test Guideline 439)
Serious eye damage/eye irritation
Eyes - Bovine cornea
Result: Causes serious eye damage. - 4 h
(OECD Test Guideline 437)
Respiratory or skin sensitization
Maximization Test - Guinea pig
Result: negative
(OECD Test Guideline 406)
Germ cell mutagenicity
Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 490
Result: negative
Test Type: Ames test
Test system: Escherichia coli/Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
Test Type: Mutagenicity (mammal cell test): micronucleus.
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 487
Result: negative
Carcinogenicity
No data available
Reproductive toxicity
No data available
Specific target organ toxicity - single exposure
No data available

Specific target organ toxicity - repeated exposure
No data available
Aspiration hazard
No data available

Section-11. Ecological Information

Toxicity
Toxicity to fish static test LC50 - Oncorhynchus mykiss (rainbow trout) - > 100 mg/l - 96 h
(OECD Test Guideline 203)
Toxicity to daphnia and other aquatic invertebrates
static test EC50 - Daphnia magna (Water flea) - > 100 mg/l - 48 h
(OECD Test Guideline 202)
Toxicity to algae static test ErC50 - Desmodesmus subspicatus (green algae) - 72 mg/l - 72 h
(OECD Test Guideline 201)
Toxicity to bacteria static test EC50 - activated sludge - > 1.000 mg/l - 30 min
(OECD Test Guideline 209)
Persistence and degradability
Biodegradability Result: 85 % - Readily biodegradable.
(OECD Test Guideline 301B)
Bioaccumulative potential
No bioaccumulation is to be expected (log Pow <= 4).
Mobility in soil
No data available
Results of PBT and vPvB assessment
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Endocrine disrupting properties
Product:
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.7 Other adverse effects
Discharge into the environment must be avoided.

Section-12. Disposal Considerations

Waste treatment methods
Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Contaminated packaging
Dispose of as unused product.

Section-13. Transport Information

UN number

ADR/RID: - IMDG: - IATA: -

UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

Packaging group

ADR/RID: - IMDG: - IATA: -

Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

Special precautions for user

No data available

Further information

Not classified as dangerous in the meaning of transport regulations.

Section-14. Regulatory Information

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

This material safety data sheet complies with the requirements of Regulation (EC) No.1907/2006.

Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

Section-15. Other Information

Important Notice

Information applies only to this material of its intended use.

The PILT prepares the MSDS by using information available at the time from sources considerable, reliable, such as PILT approved summaries of product characteristics, RTECS and the MSDS of the suppliers, manufacturers or importers. The PILT does not independently verify the information. The accuracy of the information can't therefore be guaranteed, nor does it constitute any expression of opinion by the PILT concerning the Reference Material preparation. This information is accordingly not to be regarded as a representation or statement concerning the quality or safety of the Reference Material, the presence of any defect in it, or its fitness for any particular purpose except that of use as a IPRS by professional persons having technical skill and at their own discretion andrisk. The downstream users have the responsibility to manage the risks arising from their usage ofthe PILT Reference Materialand for use of any information provided in this MSDS. People working with any reference material should apply regional and national laws, good practices and state of the art precautions.