

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/A-007/23/017

ASCORBIC ACID

STRUCTURE:

DESCRIPTION & IDENTIFICATION:

Batch No.: PILTRS/23/01/017	Ref./Product No.: A- 007
Unit Quantity: 1 gm	Chemical Formula: C ₆ H ₈ O ₆
Molecular Weight: 176.10 g/mol	Assigned Value (Purity): 99.99 % w/w or
	1.000 mg per mg on as is basis
Date of Release: 20/12/2023	$\mathbf{u}_{\text{CRM}}(\%) = 0.17 \%$
Validity Date : 19/12/2026	Method: IP 2022 AND USP 43
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.







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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 & United States Pharmacopoeia. CRM/RM lot IPRSA005 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.

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 : Ascorbic Acid

Product No. : A-007

Uses : Laboratory chemicals, Reference Material

Section-2. Hazards Identification

Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

Label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards

This substance/mixture contains no components considered to be persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information:

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.

Toxicological information:

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.

May form explosible dust-air mixture if dispersed.

Section-3. First Aid Measures

First aid measures

Description of first-aid measures

If inhaled

After inhalation: fresh air. **In case of skin contact**

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling

Indication of any immediate medical attention and special treatment needed

No data available

Section-4. Fire and Explosion Data

Extinguishing media:

Suitable extinguishing media

Water Foam Carbon dioxide (CO2) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

Special hazards arising from the substance or mixture

Carbon oxides

Combustible.

Risk of dust explosion.

Development of hazardous combustion gases or vapours possible in the event of fire.

Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system.

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 stateb) Colorc) white

c) Odor : No data available
 d) Melting point/freezing point : Melting point: 193 °C
 e) Initial boiling point and : No data available

boiling range

f) Flammability (solid, gas) : No data available g) Upper/lower flammability : No data available

or explosive limits

h) Flash point
i) Auto ignition temperature
j) Decomposition temperature
k) pH
i) No data available
k) No data available

1) Viscosity : Viscosity, kinematic: No data available: Viscosity, dynamic: No data available

m) Water solubility : No data available n) Partition coefficient : No data available

n-octanol/water

o) Vapor pressure
 p) Density
 Relative density
 : No data available
 : No data available

q) Relative vapor density

r) Particle characteristics : No data availables) 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 - 11.900 mg/kg

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Lacrimation.

Behavioral:Somnolence (general depressed activity).

Diarrhea (RTECS)

Inhalation: No data available Dermal: No data available Skin corrosion/irritation

Skin - Rabbit

Result: No skin irritation (OECD Test Guideline 404)

Serious eye damage/eye irritation

Eves - Rabbit

Result: slight irritation (OECD Test Guideline 405)

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available 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 : LC50 - Oncorhynchus mykiss (rainbow trout) - 1.020 mg/l - 96 h

(OECD Test Guideline 203)

Remarks: acidic

Toxicity to daphnia : EC50 - Daphnia magna (Water flea) - 360 mg/l - 48 h

and other aquatic

Remarks: (External MSDS)

invertebrates

Toxicity to algae : IC50 - Desmodesmus subspicatus (green algae) - 1.750 mg/l - 72 h

Remarks: (External MSDS)

: EC50 - Pseudomonas putida - 140 mg/l - 16 h Toxicity to bacteria

Remarks: (External MSDS)

Persistence and degradability

Biodegradability : Result- 97 % Readily eliminated from water

(OECD Test Guideline 302B)

Ratio BOD/ThBOD : 65 %

Remarks: Closed Bottle test(own results)

Ratio BOD/ThBOD

Remarks: Closed Bottle test(own results)

Bio accumulative potential

No data available

Mobility in soil

No data available

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 of the 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.