



SAFETY DATA SHEET

according to Directive 67/548/EC and Regulation 1907/2006/EC as amended

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY/UNDERTAKING

PRIMAQUINE DIPHOSPHATE CRS European Directorate for the Quality of Medicines & HealthCare

European Pharmacopoeia (Ph. Eur.)

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For any questions: www.edqm.eu (HelpDesk)

Catalogue code: P2940000

<u>Use</u>: For laboratory tests and assays only, as described in the European Pharmacopoeia.

2. HAZARDS IDENTIFICATION

Toxic if swallowed. May cause haematological disorders. May induce gastro-intestinal disturbances. May affect central nervous and cardiovascular systems. May cause allergic reactions.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Primaquine diphosphate $C_{15}H_{27}N_3O_9P_2$ M_r 455.3

CAS: 63-45-6 EC No: 200-560-8 EC Index number: None

NB: Anti-malaria agent.

Symbol: T R phrases: R25

4. FIRST AID MEASURES

Inhalation: Remove to fresh air. If breathing becomes difficult, call a physician.

Skin contact: Flush with copious amounts of water and soap for at least 15 minutes. Remove contaminated clothing

and shoes.

Eyes contact: Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water

for at least 15 minutes.

Ingestion: Wash out mouth with water and administer fresh water provided that the person is conscious.

Monitor respiration and pulse.

In case of reactions described in hazards identification / toxicological information or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

5. FIRE FIGHTING MEASURES

Extinguishing media: Carbon dioxide, dry chemical powder or appropriate foam. Water spray. Avoid spill into drains, surface-

and groundwater and soil.

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Emits toxic fumes under fire conditions. Risk of dust explosion cannot be excluded.

Dangerous combustion

products: CO_x , NO_x , PO_x and other noxious gases or vapours in case of incomplete combustion.

6. ACCIDENTAL RELEASE MEASURES

Switch off electrical equipment and any other sources of ignition. Evacuate area. Wear self-contained breathing apparatus, appropriate boots and heavy rubber gloves. Collect residues manually, wipe with a small quantity of water, place in a bag and hold for waste disposal. Avoid raising dust/mist. Ventilate area and wash spill site with water after material pick up is complete. Keep away from drains, surface- and groundwater and soil.

7. HANDLING AND STORAGE

Ensure adequate ventilation.

Handling: Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure.

Avoid use with incompatible materials. Recommended for quality reasons: Handle protected from light.

Storage: This CRS/BRP is not intended for long-term storage. Keep unopened and tightly closed in the original

container protected from incompatible materials, heat direct sunlight and sources of ignition.

Recommended for quality reasons: Keep protected from light at about 2-8 °C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Handling of small quantities in fume hood recommended. Mechanical exhaust, safety shower and eye bath required.

Respiratory protection: Protecting mask (filter P3), if sole means of protection.

Hand protection: Compatible chemical-resistant gloves. Eye protection: Wear protective chemical safety goggles.

Skin protection: Wear protective suit.

9. PHYSICAL AND CHEMICALS PROPERTIES

Appearance: Orange crystalline powder.

Solubility: Soluble in water, practically insoluble in ethanol (96 per cent).

Melting point: About 200 °C PH: No data available. Log Pow: No data available.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended conditions of use.

Conditions to avoid: Light.

Materials to avoid: Strong oxidizing agents.

Dangerous decomposition

products: CO_x, NO_x, PO_x, H₃PO₄ and other substances in case of incomplete decomposition.

Hazardous polymerisation will not occur.

11. TOXICOLOGICAL INFORMATION

RTECS No: VA9660000

See actual entry in RTECS for complete information.

LD50 (oral-rat): 177 mg/kg

Rapidly absorbed following ingestion. Its elimination half-life is estimated between 3 and 6 hours. Toxic if swallowed. May cause haematological disorders. May induce gastro-intestinal disturbances. May affect central nervous and cardiovascular systems. May cause allergic reactions.

Some foetotoxicity has been shown during studies on animals only at maternally toxic doses. Risk of carcinogenicity, mutagenicity, sensitisation and narcosis cannot be excluded.

12. ECOLOGICAL INFORMATION

Ecotoxicity: No data available.

Biodegradation: No data available.

Bioaccumulation and mobility:

Log Pow: Soluble in water, mobile substance, likely to migrate into aquatic environment.

13. DISPOSAL CONSIDERATIONS

Incinerate in an approved facility.

Observe all regional, national, federal state and local environmental regulations.

14. TRANSPORT INFORMATION

Transport regulation	UN Classification: UN number shipping name – Class (other risk)– PG
IATA/ICAO (air)	UN 2811 Toxic solid, organic, n.o.s. – Class 6.1 – PG III
ADR/RID (road/railway)	UN 2811 Toxic solid, organic, n.o.s. – Class 6.1 – PG III
IMDG (sea)	UN 2811 Toxic solid, organic, n.o.s. – Class 6.1 – PG III

Marine pollutant: Not classified

15. REGULATORY INFORMATION



R phrases:

R25 Toxic if swallowed.

S phrases:

S36/37 Wear suitable protective clothing and gloves.

In case of accident or if you feel unwell, seek medical advice immediately. Show the label where possible.

16. OTHER INFORMATION

Reason for update:

Revision according to Regulation (EC) No 1907/2006. New name and address of the EDQM.

R25 Toxic if swallowed.

Warning! Reference Standards - important notice.

Information applies only to the CRS/BRP for its intended use. The EDQM staff assembles the MSDSs by using the information available at the time from sources considered reliable, such as, the European Chemical Substances Information System, approved Summaries of Product Characteristics, RTECS and the MSDS of the suppliers, manufacturers or importers. The Ph. Eur does not independently verify the information. The accuracy of the information cannot therefore be guaranteed, nor does it constitute any expression of opinion by the Ph. Eur. concerning the substance/preparation. This information is accordingly not to be regarded as a representation or statement concerning the quality or safety of the substance, the presence of any defect in it, or its fitness for any particular purpose except that of use as a Ph. Eur. CRS/BRP by professional persons having technical skill and at their own discretion and risk. The downstream users have the responsibility to manage the risks arising from their uses of the Ph. Eur. Reference Standards and for use of any information provided in this SDS. People working with any reference materials should apply regional and national laws, good practises and state-of-the-art precautions.