Material Safety Data Sheet

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Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

PARAMETHADIONE

Catalog Number: 1497000 **Revision Date:** May 5, 2010

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Paramethadione

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW - Reproductive Hazard.

Adverse Effects: Adverse effects may include changes in vision; dizziness; drowsiness; headache; blood pressure changes; irritability; stomach pain; loss of appetite; mood changes; hair loss; increased sensitivity of eyes to light; hiccups; trouble sleeping; lightheadedness; vomiting; tingling, burning, or prickling sensation; nausea; unusual weakness, and unusual weight loss. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Symptoms of overdose may include clumsiness, severe dizziness, severe drowsiness, severe nausea, visual disturbances, and coma.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, blood disorders, and liver or kidney function impairment.

Cross Sensitivity: Persons sensitive to one dione anticonvulsant may be sensitive to this material also.

Target Organs: n/f

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Paramethadione

Formula: C7H11NO3

n/f = not found

Synonym: n/f

Chemical Name: 2,4-Oxazolidinedione, 5-ethyl-3,5-dimethyl-

CAS: 115-67-3

RTECS Number: RP9800000

Chemical Family: Oxazole derivative

Therapeutic Category: Anticonvulsant

Composition: Pure material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water. This material is rapidly absorbed from the gastrointestinal tract.

General First Aid Procedures: 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. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

Note to Physicians

Overdose Treatment: Treatment of overdose should be symptomatic and supportive and may include the following:
1. Evacuate stomach by induced vomiting or gastric lavage.
2. Administer charcoal as a slurry.
3. Alkalinization of urine may enhance excretion.
4. For seizures, administer a benzodiazepine IV. Consider phenobarbital or propofol if seizures recur.
5. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation.

Evaluate for hypoglycemia, electrolyte disturbances, hypoxia, and liver and kidney function. [USP DI 2003; Meditext 2010; HSDB 2010]

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing vapor. Place spillage in appropriately labeled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: 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 aerosol-generating procedures.

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 US regulation OSHA 29 CFR 1910.134).

Gloves: Chemically compatible. 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.

Eye Protection: Safety glasses with sideshields 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.

Protective Clothing: 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.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: Clear, colorless liquid; fruity odor.

Odor Threshold: n/f

pH: 6 (1 in 40 solution)

Melting Range: 31 - 32° C

Boiling Point: 151 - 152° C @ 17 mm Hg

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: Very low

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: 1.118 - 1.124

Solubility in Water: Sparingly soluble

Fat Solubility: n/f

Other Solubility: Freely soluble in alcohol, in benzene, in chloroform, and in ether.

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: 100%

Reactivity in Water: n/f

Explosive Properties: n/f

n/f = not found

Oxidizing Properties: n/f

Formula: C7H11NO3

Molecular Weight: 157.17

n/f = not found

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: n/f

Incompatibilities: n/f

Decomposition Products: When heated to decomposition, material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: n/f

Oral Mouse: LD50: 1000 mg/kg

Other Toxicity Data: n/f

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: n/f

Mutagenicity Data: n/f

Reproductive and Developmental Effects: Reports have shown increased incidence of congenital defects and fetal death occurring with paramethadione given during pregnancy. These defects include cleft lip or palate, cardiac malformations, malformed ears, irregular teeth, developmental delay, mental retardation, and speech disturbances.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State, and local laws.

SECTION 14 -TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: California Proposition 65: Developmental Toxicity

International Regulatory Information: EINECS # 204-098-8

SECTION 16 - OTHER INFORMATION

Revision: 05-May-10

n/f = not found

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