# SAFETY DATA SHEET

## 1. Identification

**Product identifier** **Fosphenytoin Sodium**

**Other means of identification**

**Catalog number** 1286366

**CAS number** 2214317-48-1

**Chemical name** Sodium (2,5-dioxo-4,4-diphenylimidazolidin-1-yl)methyl phosphate heptahydrate

**Recommended use** For analytical laboratory use only.

**Recommended restrictions** Not for use as a drug. Not for administration to humans or animals.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

**Company name** U. S. Pharmacopeia

**Address** 12601 Twinbrook Parkway
Rockville
MD
20852-1790
United States

**Telephone** Technical Services 301-816-8129

**Website** www.usp.org

**E-mail** RSTECH@usp.org

**Emergency phone number** CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards**

| | |
|---|---|
| Acute toxicity, oral | Category 4 |
| Carcinogenicity | Category 2 |
| Reproductive toxicity | Category 1B |

**Environmental hazards** Not classified.

**OSHA defined hazards** Not classified.

**Label elements**

**Signal word** Danger

**Hazard statement** Harmful if swallowed. Suspected of causing cancer. May damage fertility or the unborn child.

**Precautionary statement**

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention.

**Storage** Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** Pharmacologically active material.

## 3. Composition/information on ingredients

**Substance**

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|---|---|
| Fosphenytoin Sodium | | 2214317-48-1 | 100 |

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

## 4. First-aid measures

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact** Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact** Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion** Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

**Most important symptoms/effects, acute and delayed** Central nervous system effects. Pharmacologically active material. Occupational exposure may cause physiological effects.

**Indication of immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically. Treatment of hydantoin anticonvulsant overdose may include the following: Administer activated charcoal as a slurry. Repeat oral charcoal doses may enhance total body clearance and elimination. Perform gastric lavage soon after ingestions (within one hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first. Hemodialysis and hemoperfusion are of little benefit. Forced diuresis, peritoneal dialysis, exchange transfusions, and plasmapheresis are ineffective.

**General information** 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.

## 5. Fire-fighting measures

**Suitable extinguishing media** Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media** None known.

**Specific hazards arising from the chemical** No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters** Wear suitable protective equipment.

**Fire fighting equipment/instructions** Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** No unusual fire or explosion hazards noted.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up** Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

**Precautions for safe handling** As a general rule, when handling USP materials, 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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**Conditions for safe storage, including any incompatibilities** Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**Exposure limit values**

**Industrial Use**

| Material | Type | Value |
|---|---|---|
| Fosphenytoin Sodium (CAS 2214317-48-1) | TWA | 0.3 mg/m3 |

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls** For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection**

**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 solvent.

**Other** Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection** Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** Handling practices in this SDS are recommendations for laboratory use of USP materials.

## 9. Physical and chemical properties

**Appearance** Appearance descriptions are general information and not specific to any USP lot.

**Physical state** Solid.

**Form** Powder.

**Color** White.

**Odor** Odorless.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** 428 °F (220 °C)

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Explosive limit - lower (%)** Not available.

**Explosive limit - upper (%)** Not available.

| | |
|---|---|
| **Vapor pressure** | Not available. |
| **Vapor density** | Not available. |
| **Relative density** | Not available. |
| **Solubility(ies)** | |
| **Solubility (water)** | Freely soluble. |
| **Solubility (other)** | Chloroform: Insoluble.<br>Ethanol: Soluble.<br>Ether: Insoluble. |
| **Auto-ignition temperature** | Not available. |
| **Decomposition temperature** | Not available. |
| **Viscosity** | Not available. |
| **Other information** | |
| **Chemical family** | Hydantoin. |
| **Molecular formula** | C16H13N2Na2O6P • 7H2O |
| **Molecular weight** | 532.35 |
| **pH in aqueous solution** | 8.5 - 9.5 Solution: 7.5% |

## 10. Stability and reactivity

| | |
|---|---|
| **Reactivity** | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| **Chemical stability** | Material is stable under normal conditions. |
| **Possibility of hazardous reactions** | No dangerous reaction known under conditions of normal use. |
| **Conditions to avoid** | Contact with incompatible materials. |
| **Incompatible materials** | Strong oxidizing agents. |
| **Hazardous decomposition products** | NaOx. NOx. POx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

## 11. Toxicological information

**Information on likely routes of exposure**

| | |
|---|---|
| **Inhalation** | Knowledge about health hazard is incomplete. |
| **Skin contact** | Knowledge about health hazard is incomplete. |
| **Eye contact** | Knowledge about health hazard is incomplete. |
| **Ingestion** | Harmful if swallowed. |
| **Symptoms related to the physical, chemical and toxicological characteristics** | Hydantoin anticonvulsants: Central nervous system depression. Mental or mood changes. Nausea. Rash. Uncontrolled eye movements. Dizziness. |

**Information on toxicological effects**

| | |
|---|---|
| **Acute toxicity** | Harmful if swallowed. A related material showed oral toxicity in animals. |
| **Skin corrosion/irritation** | Knowledge about health hazard is incomplete. |
| **Serious eye damage/eye irritation** | Knowledge about health hazard is incomplete. |
| **Respiratory or skin sensitization** | |
| **Respiratory sensitization** | Knowledge about sensitization hazard is incomplete. |
| **Skin sensitization** | Knowledge about sensitization hazard is incomplete. |
| **Germ cell mutagenicity** | Knowledge about mutagenicity is incomplete. |

**Mutagenicity**

Chinese hamster lung cells
Result: Negative.
Mouse bone marrow micronucleus test
Result: Negative.
S. typhimurium Ames assay
Result: Negative.
V79 Chinese hamster lung cell chromosomal aberration
Result: Positive (with activation).

| | |
|---|---|
| **Carcinogenicity** | Suspected of causing cancer.<br>This material is related to phenytoin, which is a possible human carcinogen. There have been a number of reports suggesting a relationship between phenytoin and the development of lymphadenopathy (local or generalized), including benign lymph node hyperplasia, pseudolymphoma, lymphoma, and Hodgkin's disease. |

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

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|---|---|
| **Reproductive toxicity** | May damage fertility or the unborn child.<br>Therapeutic use of phenytoin and other hydantoin anticonvulsants during pregnancy may result in birth defects and adverse developmental outcomes in the offspring. However, a definite cause and effect relationship has not been established. Exposure to phenytoin and other hydantoins prior to delivery may lead to serious bleeding problems in the mother and baby. |
| **Specific target organ toxicity - single exposure** | Knowledge about health hazard is incomplete. |
| **Specific target organ toxicity - repeated exposure** | Knowledge about health hazard is incomplete. |
| **Aspiration hazard** | Based on available data, the classification criteria are not met. |
| **Further information** | Pharmacologically active material. Occupational exposure may cause physiological effects. |

## 12. Ecological information

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|---|---|
| **Ecotoxicity** | The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. |
| **Persistence and degradability** | No data is available on the degradability of this substance. |
| **Bioaccumulative potential** | No data available. |
| **Mobility in soil** | No data available. |
| **Other adverse effects** | No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component. |

## 13. Disposal considerations

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|---|---|
| **Disposal instructions** | Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. |
| **Local disposal regulations** | Dispose in accordance with all applicable regulations. |
| **Hazardous waste code** | The waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| **Waste from residues / unused products** | Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). |
| **Contaminated packaging** | Since emptied containers may retain product residue, follow label warnings even after container is emptied. |

## 14. Transport information

**DOT**

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

| | |
|---|---|
| **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** | Not applicable. |
| **General information** | It is the shipper's responsibility to determine the correct transport classification at the time of shipment. |

## 15. Regulatory information

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|---|---|
| **US federal regulations** | This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. |

**Toxic Substances Control Act (TSCA)**

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**SARA 302 Extremely hazardous substance**

Not listed.

| | |
|---|---|
| **SARA 311/312 Hazardous chemical** | Yes |
| **Classified hazard categories** | Acute toxicity (any route of exposure)<br>Carcinogenicity<br>Reproductive toxicity |

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

| | |
|---|---|
| **Safe Drinking Water Act (SDWA)** | Not regulated. |

**US state regulations**

**California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|---|---|---|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

| | |
|---|---|
| **Issue date** | 06-12-2008 |
| **Revision date** | 10-06-2021 |
| **Version #** | 04 |

**Disclaimer**

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