

## SAFETY DATA SHEET

Preparation Date: 11/8/2017

Revision Date: 11/8/2017

Revision Number: G1

### 1. IDENTIFICATION

#### Product identifier

**Product code:** P1094  
**Product Name:** PHENYTOIN SODIUM, USP

#### Other means of identification

**Synonyms:** 5,5-Diphenylhydantoin Sodium Salt  
 Diphenylhydantoin sodium  
 2,4-Imidazolidinedione, 5,5-diphenyl-, monosodium salt

Sodium diphenylhydantoin  
 Sodium diphenyl hydantoinate  
 Sodium 5,5-diphenylhydantoinate  
 Sodium 5,5-diphenyl-2,4-imidazolidinedione  
 Sodium phenytoin  
 Dilantin

**CAS #:** 630-93-3  
**RTECS #** MU1400000  
**CI#:** Not available

#### Recommended use of the chemical and restrictions on use

**Recommended use:** No information available.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Martin LaBenz (West Coast)  
**Contact Person:** Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Skin sensitization	Category 1
Carcinogenicity	Category 2
Reproductive toxicity	Category 2

#### Label elements

**Product code:** P1094

**Product name:** PHENYTOIN  
 SODIUM, USP

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**Danger**

**Hazard statements**

Harmful if swallowed  
May cause an allergic skin reaction  
Suspected of damaging fertility or the unborn child  
Suspected of causing cancer



**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

Not available

**Precautionary Statements - Prevention**

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Wear protective gloves/protective clothing/eye protection/face protection  
Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Contaminated work clothing must not be allowed out of the workplace

**Precautionary Statements - Response**

*IF exposed or concerned: Get medical advice/attention*  
IF ON SKIN: Wash with plenty of water  
Wash contaminated clothing before reuse  
If skin irritation or rash occurs: Get medical advice/attention  
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
Rinse mouth

**Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %
Phenytoin Sodium	630-93-3	100

**4. FIRST AID MEASURES**

**First aid measures**

**General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

**Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothing and

shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

**Most important symptoms and effects, both acute and delayed**

**Symptoms**

- May cause eye/skin/respiratory tract irritation
- May cause nausea, headache, vomiting
- Abdominal pain
- May cause constipation
- Skin rash
- Peripheral neuropathy
- Paresthesia (numbness and tingling of the extremities)
- Blurred vision
- May cause involuntary eye movements
- May affect the cardiovascular system
- Central nervous system effects
- May cause drowsiness or dizziness
- Weakness
- Tremors
- Ataxia
- Confusion
- Convulsions
- Insomnia
- May cause personality and mood changes
- May cause depression
- May affect the blood
- May affect the liver
- May cause an allergic skin reaction
- May cause allergic contact dermatitis
- May cause hyperglycemia
- Joint pain

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray mist or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides. Sodium Oxides.

**Specific hazards:** May be combustible at high temperatures.

### **Special Protective Actions for Firefighters**

**Specific Methods:** No information available.

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## **6. ACCIDENTAL RELEASE MEASURES**

### **Personal precautions, protective equipment and emergency procedures**

**Personal Precautions:** Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas.

### **Methods and material for containment and cleaning up**

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Use appropriate tools to put the spilled solid in a suitable waste disposal container. Clean contaminated surface thoroughly.

## **7. HANDLING AND STORAGE**

### **Precautions for safe handling**

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

#### **Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust.

### **Conditions for safe storage, including any incompatibilities**

#### **Technical Measures/Storage Conditions:**

Keep container tightly closed. Keep in a well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

#### **Incompatible Materials:**

Strong oxidizing agents  
Acids

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **Control parameters**

### **National occupational exposure limits**

## United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Phenytoin Sodium	630-93-3	None	None	None	None

## Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Phenytoin Sodium	630-93-3	None	None	None	None

## Australia and Mexico

Components	CAS-No.	Australia	Mexico
Phenytoin Sodium	630-93-3	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

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

#### Personal Protective Equipment

- Eye protection:** Goggles or Safety glasses with side-shields
- Skin and body protection:** Gloves  
Long sleeved clothing  
Chemical resistant apron
- Respiratory protection:** Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
- Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state:**

Solid

**Appearance:**

Powder.

**Color:**

White.

**Odor:**

Odorless.

**Taste**

No information available.

**Formula:**

C15-H12-N2-Na-O2

**Molecular/Formula weight:**

274.35 g/mole

**Flammability:**

No information available

**Flashpoint (°C/°F):**

No information available.

**Flash Point Tested according to:**

Not available

**Autoignition Temperature (°C/°F):**

No information available

**Lower Explosion Limit (%):**

No information available

**Upper Explosion Limit (%):**  
No information available

**Melting point/range(°C/°F):**  
>300 °C (>572 °F)

**Decomposition temperature(°C/°F):**  
No information available

**Boiling point/range(°C/°F):**  
No information available

**Bulk density:**  
No information available

**Density (g/cm3):**  
No information available

**Specific gravity:**  
No information available

**pH:**  
No information available

**Vapor pressure @ 20°C (kPa):**  
No information available

**Evaporation rate:**  
No information available

**Vapor density:**  
No information available

**VOC content (g/L):**  
No information available

**Odor threshold (ppm):**  
No information available

**Partition coefficient  
(n-octanol/water):**  
2.47

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Freely soluble in water  
Soluble in Alcohol  
Practically insoluble in Chloroform  
Practically insoluble in Ether  
Practically insoluble in Dichloromethane

## 10. STABILITY AND REACTIVITY

### Reactivity

May react with strong oxidizers

### Chemical stability

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Excess Heat. Avoid dust formation. Incompatible materials.

**Incompatible Materials:** Strong oxidizing agents  
Acids

**Hazardous decomposition products:** No information available.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**  
Ingestion. Inhalation.

### Acute Toxicity

### Component Information

**Product code:** P1094

**Product name:** PHENYTOIN  
SODIUM, USP

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Phenytoin Sodium	
CAS-No.	630-93-3

**LD50/oral/rat** = 1530 mg/kg Oral LD50 Rat  
**LD50/oral/mouse** = 165 mg/kg  
**LD50/dermal/rabbit** = No information available  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50 information** = No information available

**Product Information**

**LD50/oral/rat** =  
**VALUE- Acute Tox Oral** = 1530 mg/kg

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = 165 mg/kg

**LD50/dermal/rabbit**  
**VALUE-Acute Tox Dermal** = No information available

**LD50/dermal/rat**  
**VALUE -Acute Tox Dermal** = No information available

**LC50/inhalation/rat**  
**VALUE-Vapor** = No information available  
**VALUE-Gas** = No information available  
**VALUE-Dust/Mist** = No information available

**LC50/Inhalation/mouse**  
**VALUE-Vapor** = No information available  
**VALUE - Gas** = No information available  
**VALUE - Dust/Mist** = No information available

**Symptoms**

**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Inhalation** May cause irritation of respiratory tract.

**Ingestion** Harmful if swallowed. May cause headache, nausea, vomiting. May cause abdominal pain. May cause constipation. May cause thirst. May cause hyperglycemia. May affect liver. May cause skin rash, redness or itching. May cause blurred or foggy vision. May cause difficulty breathing. May cause chest pain. May affect the cardiovascular system (cardiac arrhythmias). May affect the cardiovascular system (hypotension). May cause nystagmus (involuntary eye movements). May affect behavior/central nervous system (tiredness). It may affect behavior/central nervous system (drowsiness). May affect behavior/central nervous system (ataxia, irritability, somnolence). It may affect behavior/central nervous system (excitement, depression, general anesthetic, headache, dizziness, convulsions/seizures, confusion, insomnia, muscle weakness). It may cause twitching or tremors/trembling. May cause muscle weakness and/or muscle pain. May cause joint pain.

**Ingestion:** May cause nervousness, mood changes, depression, suicidal thoughts/attempts, thoughts of harming yourself

**Aspiration hazard** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Chronic Toxicity** Prolonged or repeated ingestion may affect behavior/central nervous system. Skin: Prolonged or repeated skin contact may cause allergic skin reaction. Prolonged or repeated ingestion may affect the blood (leukopenia, thrombocytopenia). Chronic exposure may affect the peripheral nervous system (peripheral neuropathy with muscle weakness, paresthesia - a sensation of tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles) generally of the hands and feet (extremities).

**Sensitization:** May cause sensitization by skin contact.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Possibly carcinogenic to humans. Suspected of causing cancer.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Phenytoin Sodium	630-93-3	Group 2B - Possibly Carcinogenic to Humans - Monograph 66 [1996] Phenytoin	Not listed	Not listed	Present	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*Group 2B - Possibly Carcinogenic to Humans*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** Suspected of damaging fertility or the unborn child

**Reproductive Effects:** May cause adverse reproductive effects based on animal data  
**Developmental Effects:** May cause adverse developmental effects based on animal data  
**Teratogenic Effects:** May cause birth defects (teratogenic effects)

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Target Organs:** Nervous system. Liver. Blood.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

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**Product name:** PHENYTOIN  
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**Mobility:** No information available.

### 13. DISPOSAL CONSIDERATIONS

#### Disposal Methods

**Waste from residues / unused products:**

Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Phenytoin Sodium	630-93-3	None	None	None	None

### 14. TRANSPORT INFORMATION

**DOT**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Class** No information available  
**Packing group:** No information available  
**Emergency Response Guide Number** No information available  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

**TDG (Canada)**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No Information available  
**Description:** No information available

**ADR**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Packing Group:** No information available  
**Subsidiary Risk:** No information available

**IMO / IMDG**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

**RID**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**ICAO**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**IATA**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**ERG Code:** No information available  
**Special Provisions** No information available

<b>15. REGULATORY INFORMATION</b>
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**International Inventories**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Phenytoin Sodium</i>	630-93-3	Present	Present KE-12075	Not present	Not present	Not present	Present	Present 211-148-2

**U.S. Regulations***Phenytoin Sodium*

**Pennsylvania RTK:** Special hazardous substance  
**Pennsylvania RTK - Special Hazardous Substances** Present  
**New York Release Reporting - List of Hazardous Substances:**  
= 1 lb RQ  
**California Directors List of Hazardous Substances:** Present

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

WARNING: This product contains a chemical known to the State of California to cause cancer. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Phenytoin Sodium	630-93-3	carcinogen	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
<i>Phenytoin Sodium</i>	630-93-3	None	None	None	None	None

**Product code:** P1094**Product name:** PHENYTOIN  
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## U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Phenytoin Sodium	630-93-3	Not Applicable	Not Applicable

## Canada

### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

### WHMIS 1988 Hazard Class

D2A Very toxic materials  
D2B Toxic materials

### Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

## Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Phenytoin Sodium	630-93-3	Not Listed	Present

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Phenytoin Sodium	630-93-3	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Phenytoin Sodium	630-93-3	Not listed

## EU Classification

### EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Phenytoin Sodium	630-93-3	No information

### EU - CLP (1272/2008)

### R-phrase(s)

R22 - Harmful if swallowed.  
R40 - Limited evidence of a carcinogenic effect  
R43 - May cause sensitization by skin contact.  
R63 - Possible risk of harm to the unborn child.  
R68 - Possible risk of irreversible effects.

### S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label.

Components	CAS-No.	Classification	Concentration	Safety Phrases
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			<b>Limits:</b>	
Phenytoin Sodium	630-93-3		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

**Indication of danger:**

Xn - Harmful.

Xi - Irritant.

Xn



Xi



**16. OTHER INFORMATION**

Preparation Date: 11/8/2017  
Revision Date: 11/8/2017  
Prepared by: Sonia Owen

**Disclaimer:**

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**