



# Material Safety Data Sheet

## Phenytoin Sodium, Injection USP

Effective Date: 06-10-2011

Review Date: N/A

### Section 1: Chemical Product and Company Identification

**Product Name:** Phenytoin Sodium Injection, USP

**Chemical Name(s):** 5,5-Diphenyl-2,4-imidazolidione, Phenytoin

**CAS Number:** 630-93-3

**RTECS #:** n/f

**Trade Name:** Phenytoin Sodium Injection, USP

**Formula:**  $C_{15}H_{11}N_2NaO_2$

**M.W.:** 274.25

**Indication:** Phenytoin sodium injection is indicated for the control of status epilepticus of the grand mal type, and prevention and treatment of seizures occurring during neurosurgery.

#### Distributor:

X-Gen Pharmaceuticals Inc.

PO Box 445, Big Flats, NY 14814

**Technical Assistance:** 607-562-2700

### Section 2: Composition Information

#### Principle Components

Component	Weight %	UN Number	Classification
Phenytoin Sodium 630-93-3	5	None	None
Ethyl Alcohol 64-17-5	0.01	Un1170 UN1986 (flammable, toxic) UN1987 (alcohol); UN3065 (alcoholic beverages)	F;R11 S2 S7 S16
Propylene Glycol 57-55-6	0.04	None	None
Water 7732-18-5	QS	None	None

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### Section 3: Hazards Identification

**Emergency overview:** CAUTION! HARMFUL IF SWALLOWED. Do not ingest May cause eye and skin Irritation. SUSPECT CANCER HAZARD. Combustible liquid and vapor.

**Principle routes of exposure:** Absorbed through skin, Eye contact or Ingestion.

**Inhalation:** Inhalation not likely under normal use conditions.

**Ingestion:** Harmful if swallowed. Gastrointestinal effects (may include nausea, upset stomach, and loss of appetite). Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual disturbances, headache, and coma).

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

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

### Section 4: First Aid Measures

**Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

**Skin contact:** In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Seek medical attention if irritation develops.

**Ingestion:** Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

**Eye contact:** In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention if irritation develops.

**Notes to physician:** See product package insert for complete information.

### Section 5: Fire Fighting Measures

**Flash Point:** 113°F (45°C)

**Upper Flammable Limit:** n/f

**Auto-Ignition Temperature:** n/f

**Lower Flammable Limit:** n/f

**Extinguisher Media:** Use foam or all purpose dry chemicals to extinguish.

**Special protective equipment for firefighters:** Firefighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turn out gear.

**Unusual Fire and Explosion Hazards:** None

## Section 6: Accidental Release Measures

**Personnel Precautions:** Keep unnecessary personnel away. Use suitable protective clothing. (See exposure control/personnel protection)

**Environmental Precautions:** n/f

**Spill Response:** If emergency personnel are unavailable, contain spilled material. For small spills add absorbent, (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid- proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place material in an appropriate container for disposal.

## Section 7: Handling and Storage

**Handling:** Do not ingest. Wash thoroughly after handling.

**Storage:** Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F)

**Incompatibilities:** No special restrictions on storage with other products.

## Section 8: Exposure Controls / Personal Protection

Component	OSHA-Time weighted average	OSHA-Short Term Exposure limit	OSHA-Ceiling Limits	ACGIH-Weighted Average	ACGIH-Short Term Exposure limit	ACGIH-Ceiling limit Value
Phenytoin Sodium 630-93-3	None	None	None	None	None	None
Ethyl Alcohol 64-17-5	1000 ppm 1900 mg/m <sup>3</sup>	None	None	1000 ppm	None	None
Propylene Glycol 57-55-6	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

**Engineering Measures:** Provide general or local exhaust ventilation.

### Personnel Protective Equipment

**Respiratory Protection:** No personnel respiratory protective equipment normally required.

**Gloves:** Use chemical resistant, impervious gloves.

**Eye Protection:** Safety Glasses. Goggles face shield or other full-face protection if potential exists for direct exposure to aerosols or splashes.

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**Protective Clothing:** Work uniform or laboratory coat. Additional body garment should be used based upon the task being performed (e.g., sleeve lets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

### Section 9: Physical and Chemical Properties

<b>Physical State:</b> Liquid	<b>Specific Gravity:</b> n/f
<b>Appearance and Odor:</b> Aqueous solution.	<b>Color:</b> colorless.
<b>Odor:</b> n/f	<b>pH:</b> 10.0 – 12.3
<b>Melting Point:</b> n/f	<b>Evaporation rate:</b> n/f
<b>Boiling Point:</b> n/f	<b>Solubility in water:</b> n/f
<b>Vapor density:</b> n/f	<b>Viscosity:</b> n/f
<b>% Volatile by volume:</b> n/f	

### Section 10: Stability and Reactivity

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

**Incompatibility** No special restrictions on storage with other products.

**Hazardous Decomposition or Byproducts:** n/f

**Hazardous Polymerization:** n/f

**Conditions to Avoid:** Acids, Bases and Oxidizing Agents.

### Section 11: Toxicological Information

Component	LD50's and LC50's
Phenytoin Sodium 630-93-3	Oral LD50 Rat = 1530 mg/kg Oral LD50 Mouse = 165 mg/kg Intravenous LD50 = 90 mg/kg Intravenous LD50 Mouse = 98 mg/kg
Ethyl Alcohol 64-17-5	Inhalation LC50 = 20000 ppm/10h Inhalation LC50 Mouse = 39 gm/m <sup>3</sup> /4H Oral LD50 Rat = 7060 mg/kg Oral LD50 Mouse = 3450 mg/kg
Propylene Glycol 57-55-6	Oral LD50 Rat = 20 gm/kg Oral LD50 Mouse = 22 gm/kg Dermal LD50 Rabbit = 20800 mg/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

**Acute toxicity:** Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Cardiovascular effects (may include fluctuations in heart rate, changes in blood

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pressure, chest pain). Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness, blurred vision). See product package insert for additional information.

**Chronic toxicity:** n/f

**Carcinogenic effects:** May be carcinogenic. See product package insert for additional information.

**Mutagenic effects:** May be mutagenic. See product package insert for additional information.

**Reproductive toxicity:** Considered fetotoxic. See product package insert for additional information.

**FDA Pregnancy Category:** n/f

## Section 12: Ecological Information

### Environmental properties:

Component	Ecotoxicity – Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity – Freshwater Algae Data	Ecotoxicity – Microtox Data
Phenytoin Sodium 630-93-3	None	None	None	None
Ethyl Alcohol 64-17-5	None	LC50 (96 hr) rainbow trout (30 days old): 12900-15300 mg/L; Flow-through, 24-24.3°C, pH 7.56-7.60, 40.9-43.7 mg/L CaCO <sub>3</sub> ; LC50 (24 hr) fingerling trout: 11200 mg/L.; LC50 (96 hr) fathead. Minnow: 14200mg/L	None	= 34634 mg/L EC50 Photo bacterium phosphoreum = 35470 mg/L EC50 Photo bacterium phosphoreum
Propylene Glycol 57-55-6	10000 mg/L EC50 48 h	10000mg/L LC50 guppy Py48h 5000mg/L LC50 goldfish 24h	None	= 710 mg/L EC50 Photo bacterium phosphoreum
Water 7732-18-5	None	None	None	None

**Ecotoxicity effects:** n/f

**Bioaccumulation:** n/f

## Section 13: Disposal Information

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**Waste classification:**

Not regulated

**Waste from residues/unused products:**

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

#### **Section 14: Transport Information**

**DOT:**

DOT shipping name: n/f  
UN Number: n/f  
DOT Packing Group: n/f  
DOT Hazard class: n/f

**TDG (Canada):**

TDG Proper shipping name: n/f  
TDG UN/NA Number: n/f  
TDG Packing Group: n/f  
TDG Hazard class: n/f

**ADR/RID:**

ADR Official Transport Name: n/f  
ADR Proper shipping name: n/f  
ADR UN/NA number: n/f  
ADR Hazard Class: n/f

**ICAO / IATA:**

IATA Proper shipping name: n/f  
IATA UN NUMBER: n/f  
IATA Primary Hazard: n/f  
IATA Packing group: n/f  
ICAO ERG Code: n/f

**IMO / IMDG:**

IMDG Proper Shipping Name: n/f  
IMDG Hazard Class and Division: n/f  
IMDG Packing Group: n/f  
IMDG Subsidiary Risks: n/f

#### **Section 15: Regulatory Information**

**U.S. Regulations:**

**TSCA Inventory List:**

This Product is exempt from TSCA, it is FDA Regulated

Component	Weight %	RCRA Status	CERCLA Reportable Quantity	CERCLA/SARA – 302 Ext. Haz. Substances	Listed as SARA 313 Title III
Phenytoin Sodium	5	Not Listed	Not Listed	Not Listed	Not Listed
Ethyl Alcohol	0.01		Not Listed	Not Listed	Not Listed
Propylene Glycol	0.04	Not Listed	Not Listed	Not Listed	Not Listed
Water	QS	Not Listed	Not Listed	Not Listed	Not Listed

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**State Regulations:**

Component	California Prop 65	Minnesota Right-To- Know	Florida Right- To- Know	Rhode Island Right-To- Know	Massachusetts Right-To- Know	Pennsylvania Right-To- Know	New Jersey Right-To- Know
Phenytoin Sodium	Carcinogen, initial date 1/1/88	Not Listed	Not Listed	Not Listed	Not Listed	Special Hazardous Substance	Not Listed
Ethyl Alcohol	Developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)	Present	Not Listed	Toxic: Flammable	Teratogen	Present	Sn 0844
Propylene Glycol	Not Listed	Present	Not Listed	Flammable	Not Listed	Present	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

This product contains component(s) known to the State of California to cause cancer, birth defects or other reproductive harm.

**Canadian Regulations:**

**Canada DSL Inventory List -** This product complies with DSL

**EU EINECS List:** This product complies with EINECS

**Other Regulations:**

Japanese Inventory (ENCS) This product does not comply with JPENCS

**Other Classifications:**

**SARA 313 listed?** No      **CERCLA listed?** No      **RCRA listed?** n/f

**Risk Phrases:** n/f

**Safety phrases:** n/f

**Section 16: Other Information**

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**Additional information:**

Use of this product should be through or under the direction of a physician. This MSDS does not address therapeutic use of this material.

The information is believed to be accurate and represents the best information currently available to us. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use.

**Prepared by:** X-GEN Pharmaceuticals Inc., Safety Committee