

## SAFETY DATA SHEET

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

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
<b>Emergency Telephone</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
<b>Hospira, Inc., Non-Emergency</b>	224 212-2000
<b>Product Name</b>	Phenytoin Sodium Injection, USP
<b>Synonyms</b>	Sodium 5, 5-diphenyl-2, 4-imidazolidinedione

### 2. HAZARD(S) IDENTIFICATION

**Emergency Overview** Phenytoin Sodium Injection, USP, is a solution containing phenytoin sodium, a hydantoin drug used to treat epilepsy. In the workplace, this product should be considered a flammable liquid, potentially irritating to the skin and eyes, and a potential occupational reproductive hazard. Based on clinical use, possible target organs include the central nervous system, cardiovascular system, gastrointestinal system, hematopoietic system, and skin.

#### U.S. OSHA GHS Classification

Physical Hazards	Hazard Class	Hazard Category
	Flammable Liquid	4
Health Hazards	Hazard Class	Hazard Category
	Eye Damage / Irritation	2
	Toxic to Reproduction	2
	Carcinogenicity	2
	STOT - RE	2

#### Label Element(s)

**Pictogram**



**Signal Word**

Warning

**Hazard Statement(s)**

Combustible liquid  
Causes serious eye irritation  
Suspected of damaging fertility or the unborn child  
Suspected of causing cancer  
May cause damage to organs through prolonged or repeated exposure

**2. HAZARD(S) IDENTIFICATION: continued**

**Precautionary Statement(s)**

**Prevention**

Keep away from flames and hot surfaces. – No smoking  
 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  
 Do not breathe vapor or spray  
 Wash hands thoroughly after handling

**Response**

**IN CASE OF FIRE:** For small fires, use water fog or fire extinguishing media suitable for Class B fires (e.g. dry chemical, carbon dioxide or foam). For large fires, apply water from as far away as possible; use very large quantities of water applied as a mist or spray.

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.

**IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

**IF ON SKIN (OR HAIR):** Take off immediately all contaminated clothing. Rinse skin with water/shower.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

<b>Active Ingredient Name</b>	Phenytoin Sodium	Propylene Glycol	Ethyl Alcohol
<b>Chemical Formula</b>	C <sub>15</sub> H <sub>11</sub> N <sub>2</sub> O <sub>2</sub> •Na	C <sub>3</sub> H <sub>8</sub> O <sub>2</sub>	C <sub>2</sub> H <sub>6</sub> O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Phenytoin Sodium	5	630-93-3	MU1400000
Propylene Glycol	40	57-55-6	TY2000000
Ethyl Alcohol	10	64-17-5	KQ6300000

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium hydroxide which is used to adjust the pH.

**4. FIRST AID MEASURES**

<b>Eye Contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Skin Contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Ingestion</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

## 5. FIRE FIGHTING MEASURES

<b>Flammability</b>	Flash Point: 63.9°C (147°F)
<b>Fire &amp; Explosion Hazard</b>	Flammable Liquid (GHS Category 4). Keep away from flames, sparks, or other sources of ignition. When heated, product may produce combustible vapors due to the alcohol content.
<b>Extinguishing Media</b>	As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
<b>Special Fire Fighting Procedures</b>	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Spill Cleanup and Disposal</b>	Isolate area around spill. Remove potential sources of ignition. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
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## 7. HANDLING AND STORAGE

<b>Handling</b>	No special handling required for hazard control under conditions of normal product use.
<b>Storage</b>	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
<b>Special Precautions</b>	No special precautions required for hazard control.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Phenytoin Sodium	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: Not Established	8 hr TWA: Not Established
Propylene Glycol	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: 10 mg/m <sup>3</sup>	8 hr TWA: Not Established
Ethyl Alcohol	8 hr TWA: 1000 ppm; 1900 mg/m <sup>3</sup>	8 hr TWA: 1000 ppm	8-hr TWA: Not Established	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 AIHA WEEL: Workplace Environmental Exposure Level  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.

<b>Respiratory Protection</b>	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
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**8. EXPOSURE CONTROLS/PERSONAL PROTECTION: continued**

<b>Skin Protection</b>	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
<b>Eye Protection</b>	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
<b>Engineering Controls</b>	Engineering controls are normally not needed during the normal use of this product.

**9. PHYSICAL/CHEMICAL PROPERTIES**

<b>Appearance/Physical State</b>	Clear, colorless to slightly yellow solution
<b>Odor</b>	NA
<b>Odor Threshold</b>	NA
<b>pH</b>	10.0 to 12.3
<b>Melting point/Freezing Point</b>	NA
<b>Initial Boiling Point/Boiling Point Range</b>	99°C
<b>Flash Point</b>	63.9°C (147°F)
<b>Evaporation Rate</b>	NA
<b>Flammability (solid, gas)</b>	NA
<b>Upper/Lower Flammability or Explosive Limits</b>	LEL: 3.3% based on ethanol; UEL: 19% (based on ethyl alcohol)
<b>Vapor Pressure</b>	43 mm Hg at 23°C for ethyl alcohol; 0.07 mm Hg at 20°C for propylene glycol
<b>Vapor Density (Air =1)</b>	1.59 for ethyl alcohol; 2.6 for propylene glycol
<b>Relative Density</b>	1.0306
<b>Solubility</b>	Ethyl alcohol
<b>Partition Coefficient: n-octanol/water</b>	NA
<b>Auto-ignition Temperature</b>	NA
<b>Decomposition Temperature</b>	NA
<b>Viscosity</b>	NA

**10. STABILITY AND REACTIVITY**

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined
<b>Conditions to Avoid</b>	Not determined
<b>Incompatibilities</b>	Strong oxidizers, acids
<b>Hazardous Decomposition Products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity** - Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Phenytoin Sodium	100	LD50	Oral	1530 165, 490	mg/kg mg/kg	Rat Mouse
Phenytoin Sodium	100	LD50	Intravenous	90 98, 92	mg/kg mg/kg	Rat Mouse
Ethyl Alcohol	100	LD50	Oral	3450 – 11,500	mg/kg	Guinea Pig, Rat, Mouse, Dog
Ethyl Alcohol	100	LD50	Intravenous	1973	mg/kg	Mouse
Ethyl Alcohol	100	LC50 (10h)	Inhalation	20,000	ppm	Rat
Ethyl Alcohol	100	LD50 (4h)	Inhalation	39,000	mg/m <sup>3</sup>	Mouse
Propylene Glycol	100	LD50	Oral	10,400 - 29,536	mg/kg	Rat, Mouse, Rabbit, Dog, Guinea Pig
Propylene Glycol	100	LD50	Intravenous Intravenous	6423-6800 6630-8000	mg/kg mg/kg	Rat Mouse
Propylene Glycol	100	LD50	Dermal	20,800	mg/kg	Rabbit

LD 50: Dosage that produces 50% mortality.

LC50 is the concentration in air that produces 50% mortality.

**Occupational Exposure Potential**

Information on the absorption of this product via inhalation or skin contact is not available. It has been reported that phenytoin sodium may be absorbed through the skin. Avoid liquid aerosol generation and skin contact.

**Signs and Symptoms**

None anticipated from normal handling of this product. Phenytoin sodium can be irritating to the respiratory tract and solutions can cause severe eye and skin irritation. In clinical use, adverse central nervous system effects may include ataxia, slurred speech, dizziness, and headaches. Severe cardiotoxic reactions have included atrial and ventricular conduction depression and ventricular fibrillation. Adverse gastrointestinal effects may include nausea, vomiting, and constipation. Allergic-type reactions include dermatological manifestations sometimes accompanied by fever have included scarlatiniform or morbilliform rashes. Hemopoietic complications have included thrombocytopenia, leukopenia, granulocytopenia, agranulocytosis, and pancytopenia with or without bone marrow suppression. Local irritation, inflammation, tenderness, necrosis, and sloughing have been reported, with or without extravasation of intravenous phenytoin.

**Aspiration Hazard**

None anticipated from normal handling of this product.

**Dermal Irritation/ Corrosion**

None anticipated from normal handling of this product. However, inadvertent contact of this product with skin may produce irritation.

**Ocular Irritation/ Corrosion**

None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce severe irritation with redness and tearing.

**Dermal or Respiratory Sensitization**

None anticipated from normal handling of this product. Allergic-like reactions have been reported during the normal clinical use of this product.

**Reproductive Effects**

None anticipated from normal handling of this product. Phenytoin is a teratogen in rats, mice, and rabbits. Days 12 and 13 are the critical period for induction of teratogenicity in CD-1 mice. Phenytoin was not teratogenic in dogs or cats. It was fetotoxic, but not teratogenic, in monkeys at dosages where maternal toxicity was seen.

Ethyl alcohol has been shown to produce adverse effects on fetal development in laboratory animals. In humans, chronic prenatal exposure to ethanol has been associated with a distinct pattern of congenital malformations that have collectively been termed "fetal alcohol syndrome".

**11. TOXICOLOGICAL INFORMATION: continued**

<b>Mutagenicity</b>	It has been reported that phenytoin induced micronuclei in mice at an intravenous dose of 500 or 1000 mcg/kg. In other reports, phenytoin was not active for inducing chromosome aberrations in cultured Chinese hamster ovary cells. It was also inactive for inducing chromosome aberrations in bone marrow cells of mice injected with doses as high as 500 mg/kg. No increases in chromosome aberrations were seen in epileptic patients receiving long-term phenytoin or primidone therapy. No increases in sister chromatid exchanges were seen in lymphocytes of epileptic patients receiving phenytoin monotherapy in comparison with healthy controls.
<b>Carcinogenicity</b>	Elevated risks for Hodgkin's disease, lymphosarcomas, and reticulum-cell sarcoma have been seen in patients receiving phenytoin therapy. Phenytoin sodium induced thymic lymphomas in female mice when given in the diet at a level of 60 mg/kg body weight/day for 168 days. Thymic and mesenteric lymphomas and leukemias were induced in mice with intraperitoneal doses of 0.6 mg/ animal/day for 66 days. Phenytoin was not carcinogenic in rats when given in the diet at levels of 0.025 or 0.05% for 2 years. It was also not carcinogenic in mice at dietary levels of 0.006 or 0.12% for 78 weeks. Phenytoin is an IARC and NTP listed carcinogen.
<b>Carcinogen Lists</b>	<b>IARC:</b> Group 2B – Possibly Carcinogenic to Humans <b>NTP:</b> Reasonably Anticipated to be a Human Carcinogen. <b>OSHA:</b> Not listed
<b>Specific Target Organ Toxicity – Single Exposure</b>	NA
<b>Specific Target Organ Toxicity – Repeat Exposure</b>	Based on clinical use, possible target organs include the central nervous system, cardiovascular system, gastrointestinal system, hematopoietic system, and skin.

**12. ECOLOGICAL INFORMATION**

<b>Aquatic Toxicity</b>	Not determined for the product. Information for ingredients is provided below: LC50(24 hr) = 12,900 - 15,300 mg/L in rainbow trout for ethanol LC50 (24 hr) = 11,200 mg/L in fingerling trout for ethanol LC50(48 hr) = 9,268 - 14,221 mg/L in Daphnia magna for ethanol EC50 = 9310 mg/L in Chlorella pyrenoidosa (green algae) for ethanol LC50(96 hr) = 51,600 mg/L in rainbow trout for propylene glycol LC50(48 hr) = 34,400 - 43,500 mg/L in Daphnia magna for propylene glycol EC50(14 day) = 19,000 mg/L in algae for propylene glycol
<b>Persistence/Biodegradability</b>	Not determined for the product. Information for ingredients is provided below: Ethanol, an ingredient in this product, was reported to be degraded between 45% and 74% in five days in two aqueous biodegradation assays. Propylene glycol was reported to be 100% biodegradable after 24-hours in activated sludge.
<b>Bioaccumulation</b>	Not determined for the product. Because of its low octanol:water partition coefficient, ethanol is not anticipated to bioaccumulate.
<b>Mobility in Soil</b>	Not determined for product.

Notes: 1. LC50: Concentration in water that produces 50% mortality in fish or Daphnia. EC50: Concentration in water that produces 50% inhibition of growth in algae or immobilization in Daphnia.

**13. DISPOSAL CONSIDERATIONS**

<b>Waste Disposal</b>	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

**14. TRANSPORTATION INFORMATION**

<b>ADR/ADG/ DOT STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>ICAO/IATA STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>IMDG STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA

Notes: DOT - US Department of Transportation Regulations

**15. REGULATORY INFORMATION**

<b>US TSCA Status</b>	Exempt
<b>US CERCLA Status</b>	Not listed
<b>US SARA 302 Status</b>	Not listed
<b>US SARA 313 Status</b>	Not listed
<b>US RCRA Status</b>	Not listed
<b>US PROP 65 (Calif.)</b>	This product is, or contains chemical(s) known to the State of California to cause cancer and/or developmental toxicity.

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

**GHS/CLP Classification\***      \*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

<b>Hazard Class</b>	<b>Hazard Category</b>	<b>Pictogram</b>	<b>Signal Word</b>	<b>Hazard Statement</b>
NA	NA	NA	NA	NA
<b>Prevention</b>	Keep away from flames and hot surfaces. – No smoking 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 Do not breathe vapor or spray Wash hands thoroughly after handling			
<b>Response</b>	If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.  IF ON SKIN (OR HAIR): Take off immediately all contaminated clothing. Rinse skin with water/shower.  IN CASE OF FIRE: For small fires, use water fog or fire extinguishing media suitable for Class B fires (e.g. dry chemical, carbon dioxide or foam). For large fires, apply water from as far away as possible; use very large quantities of water applied as a mist or spray.			

**15. REGULATORY INFORMATION: continued**

<b><u>EU Classification*</u></b>	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
<b>Classification(s)</b>	NA
<b>Symbol</b>	NA
<b>Indication of Danger</b>	NA
<b>Risk Phrases</b>	NA
<b>Safety Phrases</b>	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

**16. OTHER INFORMATION**

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD <sub>50</sub>	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS  
 Date Prepared: October 19, 2012  
 Date Revised: June 02, 2014

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